

REMARKS

Claims 44-88 are pending. Claim 80 is deleted and new claims 89-91 are added. Thus, with the entry of this amendment, claims 44-79 and 81-91 will be active in this case.

I. **Substitute Specification**

The Examiner has requested applicants to file a Substitute Specification. Pursuant to that request, applicants herewith submit a Substitute Specification as well as a red-lined copy of the original specification indicating where all of the changes have been made. Pursuant to 37 CFR § 1.25 and MPEP 608.01(q), no new matter has been added in the Substitute Specification.

II. **Double Patenting**

Applicants acknowledge the examiner's objections for double patenting and will attend to such issues upon indication of allowable subject matter.

III. **Rejections under 35 USC § 112**

Claims 45-46, 48-88 are rejected under 35 USC §112, first paragraph, for the asserted reason that the "specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims." (page 5, first paragraph).

Specifically, the Examiner objects to the recitation in the claims of stimulatory activities. She interprets such recitation as meaning that "the claims encompass variants of the disclosed protein which has varying activities for BALB/MK cells relative to NIH/3T3 fibroblasts" (page 5, third paragraph) and that applicants intend to claim peptides with "varying degrees of stimulatory activity" (*Id.*). She concludes that it "would require undue experimentation for one of ordinary skill in the art to determine which proteins meet the structure limitation of the claims and the functional limitations." (*Id.*) Applicants respectfully traverse this rejection.

Claim 45 is directed to a polypeptide that either has the sequence of Figure 7 or is a segment of Figure 7. By "segment," applicants mean the portion of the sequence of Figure 7 that is left after a sequential deletion of amino acids, starting at the N terminus and/or C terminus. The entire protein only has 194 amino acids and the process of making and testing a truncation is the same regardless of whether the truncation is between 32 and 78 or between 78 and 194.

Applicants believe that the functional language in the present claims may have confused the examiner. Applicants do not intend there to be "varying degrees of stimulatory activity." Applicants do not mean that the skilled artisan must match a specific sequence with a specific activity, as the examiner has implied. Rather, applicants have added the differing functional language to the claims to provide a narrower test for what does or does not fall within the scope of the claims. If a single polypeptide (*i.e.*, a specific segment of the amino acid sequence of Figure 7) meets the functional limitation of one of the dependent claims, it also meets the functional limitation of the parent claim. The various functional recitations in claims 46-49, for instance, are simply alternative definitions of the term "has preferential mitogenic activity on cells of epithelial origin."

The examiner also questions the written support for the functional limitation (page 11, second paragraph). In response, applicants point out that the functional recitation of claim 45 and claims dependent therefrom is fully supported in original Table I-2. In view of this explanation, applicants respectfully request the examiner to reconsider and withdraw the rejection over the claims 45-46, 48-49, 81-82 and 84-85.

The examiner also has objected to the term "a sufficient number of amino acids 32-64 of Figure 7 to confer on said polypeptide mitogenic activity on BALB/MK cells" and therefore rejected claims 58, 63, 67 and 78. In response to this concern, applicants have herewith amended these claims to recite the functional language suggested by the examiner: "epithelial cell specificity." However, Applicants assert that such amendment changes the meaning of original language used, *i.e.* "preferential mitogenic activity on cells of epithelial origin," which means specificity for epithelial cells, such as BALB/MK cells. Rather, this change is being

made strictly to expedite prosecution. In view of this amendment, applicants respectfully request the examiner to withdraw this rejection.

The examiner also has objected to the term “conservative amino acid substitutions” in claim 78. In response, applicants have amended claim 78 to delete the allegedly offensive language. Please withdraw this rejection in view of this amendment.

The Examiner also objects to claims 74 and 75 for depending from claim 51, which recites “antibodies that selectively bind said polypeptide.” She suggests that applicants better define what is meant by selective binding or provide a length for the segment (page 9, last paragraph to page 10, first paragraph). In response, applicants have deleted “selectively” from claim 51. The specification teaches the use of KGF in the production of antibodies. In fact, such antibodies are the subject of U.S. Patent No. 5,645,405, the specification for which is the same as the present specification. The referred to amendment addresses the Examiner’s concerns set forth in Paragraph 10 of the Office Action and withdrawal of the rejection is therefore requested.

The Examiner also has rejected claims 63-69 for lacking written support in the specification for a “random selection” of amino acids. In response, applicants submit that what is intended is a segment comprising a consecutive number of amino acids. The claims have been amended, accordingly and withdrawal of the rejection is therefore requested.

In Paragraph 10 of the Office Action, the Examiner rejects claim 53 for failing to adequately define what is meant by “N terminally truncated with the region of amino acids 32-78.” In response, applicants have amended claim 53 to clarify what is intended. Withdrawal of the rejection is therefore requested.

CONCLUSION

In view of the Substitute Specification, the above amendment and remarks, applicants assert that the present claims are in condition for allowance. Early notification of allowability is therefore respectfully requested.

Respectfully submitted,

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Date

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